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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

VENCI, DAVID J

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/719,735 | MINDEN, JONATHAN SAMUEL | |
| | Examiner | Art Unit | |
| | David J. Venci | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 6, 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 10-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 25-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges Applicant's reply, filed September 6, 2006. Applicant presents new claim 38.

Currently, claims 1-9 and 25-38 are under examination. Claims 10-24 are directed to a non-elected invention and remain withdrawn from consideration pursuant to 37 CFR 1.142(b).

Specification

The disclosure is objected to because of the following informalities:

Throughout the Specification, the recitation of "half life" of binding or "half life" of release is indefinite because it is not clear how one skilled in the art can make a capture device having a specific "half-life of binding" or a specific "half life of release" when the definitions of "half-life of binding" and the "half life of release" only take into account the parameter of time (i.e. the amount of time required to covalently bind or release half the protein), and do not take into account initial concentration of reactants as well as the forward and reverse rate constants.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). In claims 2 and 28, Examiner is unable to locate original support in the specification for the subject matter encompassed by the language "substrate comprising a polymer".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-9, 25 and 27-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Schuck & Wildi (US 3,679,653).

Schuck & Wildi describe a biomolecule capture device (see Title, "Hormonally-active reaction product of a polymer with a hormone") comprising:

(a) a substrate having a surface (see Title, "polymer"); and

(b) a maleic anhydride compound (see col. 6, lines 19-28)

covalently bound to the surface of the substrate through a functional group at one of a 2 or 3 position of the maleic anhydride (see col. 5, lines 30 to col. 6, line 12, "Z is a bivalent radical", "q is zero");

having an exposed carbonyl (see col. 5, line 30) for reversible covalent binding to a biomolecule (see col. 3, lines 71-75, "the linkage is an amide[...] formed by the carboxyl or anhydride of the polymer with an amine or hydroxyl group in a non-essential moiety of the hormone protein chain" (paraphrasing mine)) under selected pH conditions (see col.

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3, lines 14-16, "[t]he pH range for the reaction[...] is usually about 5 to 9.5" (paraphrasing mine)).

With respect to claim 35, Schuck & Wildi describe a disubstituted maleic anhydride compound (see col. 5, line 30) covalently bound at one of the disubstituted positions (see col. 5, line 30, "CR_B—") to the surface of the substrate (see Title, "polymer").

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuck & Wildi (US 3,679,653) in view of Schmincke-Ott & Bisswanger, 10 PREP. BIOCHEM. 69 (1980) (abstract only).

Schuck & Wildi describe a biomolecule capture device as substantially described, *supra*, and incorporated herein.

Schuck & Wildi do not describe a device incorporating "aminohexyl agarose" or "aminododecyl agarose".

However, Schmincke-Ott & Bisswanger describe the general use of aminohexylagarose for concentrating protein solutions (see Title).

It would have been obvious for a person of ordinary skill in the art to modify the biomolecule capture device of Schuck & Wildi to include aminohexylagarose because Schmincke-Ott & Bisswanger discovered that aminohexylagarose has "high capacity" for adsorbing different proteins "with practically no losses of material or activity" (see Abstract).

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Response to Arguments

Specification

In prior Office Action, Examiner objected to the disclosure because, throughout the Specification, the recitation of "half life" of binding or "half life" of release was considered indefinite.

In response, Applicant posits that the offending phrases are "not relevant to an understanding of the claimed subject matter by those skilled" (see Applicant's reply, p. 8, fifth paragraph).

Applicant's argument is not persuasive.

According to M.P.E.P. 2161, the requirements of 35 U.S.C. 112, first paragraph, are not merely limited to claimed subject matter, but are applicable to Applicant's entire specification. Thus, Examiner posits that the aforementioned objection to the specification is maintainable insofar as Applicant's entire specification does not enable one skilled in the art to make a capture device having a specific "half-life of binding" or a specific "half life of release".

Prior Art Claim Rejections

In prior Office Action, claims 1-3, 5-9, 25 and 27-37 were rejected under 35 U.S.C. 102(b) as being anticipated by Schuck & Wildi (US 3,679,653). Claims 4 and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schuck & Wildi (US 3,679,653) in view of Schmincke-Ott & Bisswanger, 10 PREP. BIOCHEM. 69 (1980) (abstract only).

In response, Applicant argues the following:

1. Schuck & Wildi do not teach a maleic anhydride compound bound to a substrate (see Applicant's reply, p. 10, lines 19-21, "The resulting polymer of [Schuck & Wildi] is not a maleic anhydride

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compound bound to a substrate. The maleic anhydride used in [Schuck & Wildi] becomes the substrate and changes form in the process." (paraphrasing mine)).

2. Schuck & Wildi do not teach a hormone reversibly attached to a maleic anhydride (see Applicant's reply, p. 10, lines 21-22, "there is no teaching that the hormone reversibly attaches to a maleic anhydride").
3. The teachings of Schmincke-Ott & Bisswanger have nothing to do with Applicant's invention (see Applicant's reply, p. 11, second full paragraph).

Applicant's arguments have been carefully considered but are not persuasive.

With respect to 1), Schuck & Wildi describe a maleic anhydride compound (see col. 6, lines 19-28) bound to a substrate (see Title, "polymer").

With respect to 2), Schuck & Wildi describe reversibly attached hormones (see col. 2, lines 15-17, "[t]he water-insoluble polymer-hormone products provide a low but continuous release of activity for implanted systems").

With respect to 3), Examiner respectfully disagrees with Applicant's assertion. Applicant's claimed invention is directed to a "biomolecule capture device" (see preambles of claims 1-9 and 25-38, "biomolecule capture device"). Similarly, Schmincke-Ott & Bisswanger describe the general use of aminohexylagarose for capturing biomolecules (see Abstract, second sentence). The teachings of Schmincke-Ott & Bisswanger appear relevant to Applicant's invention.

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Conclusion

No claims are allowable at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv


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